

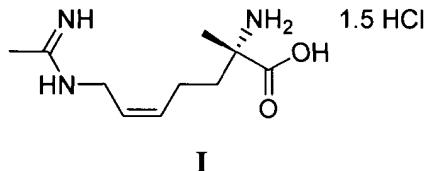
Claims

What is claimed is:

5 1. A crystal form of 2-amino-7-(ethanimidoylamino)-2-methylhept-5-enoic acid.

10 2. A crystal form of 2-amino-7-(ethanimidoylamino)-2-methylhept-5-enoic acid characterized by at least one physical measurement selected from the group consisting of: x-ray powder diffraction pattern as shown in Fig. 3, Raman spectrum as shown in Fig. 6, melting point of 224 °C and a heat of fusion of 147 joules gram⁻¹.

15 3. A compound of formula (I)



being (2S,5Z)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid, 1.5 hydrochloride or a physiologically functional derivative thereof.

20 4. A pharmaceutical composition comprising an effective amount of (2S,5Z)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid, 1.5 hydrochloride, together with a pharmaceutically acceptable carrier.

25 5. A method for the prophylaxis or treatment of a clinical condition in a mammal, such as a human, for which an inhibitor of nitric oxide synthase is indicated, which comprises administration of a therapeutically effective amount of a compound as claimed in claim 1.

or neuropathic), both acute and chronic; opiate tolerance in patients needing protracted opiate analgesics; benzodiazepine tolerance in patients taking benzodiazepines; addictive behaviors, including nicotine and eating disorders; systemic hypotension associated with septic or toxic shock; an ocular condition ; systemic lupus erythematosis (SLE); glomerulonephritis; restenosis; inflammatory sequelae of viral infections; acute respiratory distress syndrome (ARDS); oxidant-induced lung injury; complications associated with IL2 therapy; cachexia; immunosuppression; disorders of gastrointestinal motility; sunburn; eczema; psoriasis; gingivitis; pancreatitis; damage to the gastrointestinal tract resulting from infections; cystic fibrosis; treatment to a dysfunctional immune system; adenomatous polyposis; tumor growth; and bronchitis.

15

7. Use of a compound as claimed in claim 1 in the manufacture of a medicament for the prophylaxis or treatment of a clinical condition for which an inhibitor of nitric oxide synthase is indicated.

- 20 8. A method of making crystalline (2S,5Z)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid, 1.5 hydrochloride comprising the steps of:
 - (a) Obtaining a non-crystalline form of (2S,5Z)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid;
 - (b) optionally adding hydrochloric acid until the (2S,5Z)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid reaches 1.5 HCl equivalents; or
 - (c) optionally adjusting hydrochloric acid concentration with an appropriate base until the (2S,5Z)-2-amino-2- methyl-7-[(1-

- 25

iminoethyl)amino]-5-heptenoic acid reaches 1.5 HCl equivalents; or

5 (d) optionally removing any other salt counterion from the (2*S*,5*Z*)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid and adding hydrochloric acid until the (2*S*,5*Z*)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid reaches 1.5 hydrochloride equivalents;

10 (e) optionally seeding the (2*S*,5*Z*)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid, 1.5 hydrochloride obtained with crystalline (2*S*,5*Z*)-2-amino-2-methyl-7-[(1-iminoethyl)amino]-5-heptenoic acid, 1.5 hydrochloride; and

(f) optionally adding a solvent.